for the New Claims. Claims 16 and 18 have been amended to depend upon claims 27 and 28 respectively. No new matter is involved with the amendments to the claims. Applicants respectfully request the amendments be entered and all the claims of the present invention be allowed.

Restriction Requirement

The Examiner pointed out that Applicants had presented Claims 16 and 18 in improper format. New Claims 27 and 28 have been added to clearly indicate the interrelatedness of the groups comprised in Claims 16 and 18. Thus, Applicants traverse the restriction requirements of Claims 16 and 18 as not being proper species.

The Examiner has required restriction under 35 USC §121 to one of the following twenty-four groups:

I. Claim 1, drawn to a method for identifying candidate compounds for regulating skeletal muscle mass or function, comprising contacting a test compound with a VPAC receptor and determining whether the test compound binds to a VPAC receptor, classified in 435/7.1.

II. Claim 2, drawn to a method for identifying therapeutic compounds for regulating skeletal muscle mass or function, comprising contacting a test compound with a VPAC receptor, determining whether the test compound binds to a VPAC receptor, administering the test compound to a non-human animal and determining whether the test compound regulates skeletal muscle mass or function, classified in 435/7.1

III. Claims 3-8, drawn to a method for identifying candidate compounds for regulating skeletal muscle mass or function, comprising contacting a test compound with a cell expressing a VPAC receptor and determining whether the test compound activates a VPAC receptor, classified in 435/7.2.

IV. Claim 9, drawn to a method for identifying therapeutic compounds for regulating skeletal muscle mass or function, comprising contacting a test compound with a cell which expresses a functional VPAC receptor, determining whether the test compound activates a VPAC receptor, administering the test compound to a non-human animal and determining whether the test compound regulates skeletal muscle mass or function, classified in 435/7.2.

V. Claim 10, drawn to a method for identifying candidate compounds from one or more candidate compounds which have been previously determined to activate VPAC receptor, comprising administering the candidate compound to a non-

human animal and determining whether the candidate compound regulates skeletal muscle mass or function, classified in 435/7.1.

VI. Claims 11 and 12, drawn to a method for identifying candidate compounds that prolong or augment the activation of a VPAC receptor, comprising contacting a test compound with a cell which expresses a functional VPAC receptor, treating the cell with an agonist and determining the level of activation of the VPAC receptor, classified in 435/7.2

VII. Claim 13, drawn to a method for identifying candidate compounds for increasing VPAC receptor expression, comprising contacting a test compound with a cell or cell lysate containing a reporter gene operatively associated with a VPAC receptor regulatory element and detecting expression of the reporter gene, classified in 435/6.

VIII. Claim 14, drawn to a method for identifying candidate compounds for increasing the expression of VIP or a VIP analog, comprising contacting a test compound with a cell or cell lysate containing a reporter gene operatively associated with a VIP analog regulatory element and detecting expression of the reporter gene, classified in 435/6.

IX. Claim 15, drawn to a pharmaceutical composition comprising a safe and effective amount of a VPAC receptor agonist and a pharmaceutically-acceptable carrier, classified in 514/1.

X. Claims 16 (in part) and 17, drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of a VPAC receptor agonist, classified in 424/130.1.

XI. Claim 16 (in part), drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of a compound that prolongs or augments the activation of VPAC receptors or the activation of a VPAC receptor signal transduction pathway, classified in 514/1.

XII. Claim 16 (in part), drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and

effective amount of an expression vector encoding a functional VPAC receptor, classified in 514/44.

XIII. Claim 16 (in part), drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of an expression vector encoding a constitutively active VPAC receptor, classified in 514/44.

XIV. Claim 16 (in part), drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of a compound that increases expression of VPAC receptors, classified in 514/1.

XV. Claim 16 (in part), drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of a compound that increases expression of VIP, classified in 514/1.

XVI. Claim 16 (in part), drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of a compound that increases expression of a VIP analog, classified in 514/1.

XVII. Claims 18 (in part), 19-21 and 23, drawn to a method for treating skeletal muscles atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of a VPAC receptor agonist, classified in 424/130.1.

XVIII. Claims 18 (in part) and 22, drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of a compound that prolongs or augments the activation of VPAC receptors or the activation of a VPAC receptor signal transduction pathway, classified in 514/1.

XIX. Claim 18 (in part), drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle

atrophy and administering to the subject a safe and effective amount of an expression vector encoding a functional VPAC receptor, classified in 514/44.

XX. Claim 18 (in part), drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of an expression vector encoding a constitutively active VPAC receptor, classified in 514/44.

XXI. Claim 18 (in part), drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of a compound that increases expression of VPAC receptors, classified in 514/1.

XXII. Claim 18 (in part), drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of a compound that increases expression of VIP, classified in 514/1.

XXIII. Claim 18 (in part), drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of a compound that increases expression of a VIP analog, classified in 514/1.

XXIV. Claims 24-26, drawn to a purified antibody specific for the VPAC receptor, classified in class 530/387.1.

Applicants hereby elect, with traverse, to prosecute the subject matter of Group X, drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of a VPAC receptor agonist. Applicants respectfully traverse the restriction requirement. The Examiner state that Groups 1-VIII and X-XXIII are unrelated because the methods have "different methods steps, starting materials and goals." Groups IX and (X and XVII) are distinct because "the pharmaceutical composition of Group IX could be used for an entirely different purpose such as in the method of Group VI, rather than in the methods of Groups X and XVII." Lastly the Examiner asserts that Groups XXIV and (I-XXIII) are unrelated because the "antibodies of Group XXIV are not required in the methods of Groups I-VIII and X-XXIII, and they are not required to be a part of the composition of Group IX."

MPEP §803 set forth the criteria for any restriction requirement, providing that

> There are two criteria for a proper requirement for restriction between patentably distinct inventions:
> (1) The inventions must be independent or distinct as claimed; and
> (2) There must be a serious burden on the examiner if restriction is not required.

Apparently the Examiner is restricting on the basis that these inventions are independent or distinct. Applicants respectfully submits that the claims of Groups I-XXIV are so closely interrelated and in order to preserve unity of invention, all the groups should be prosecuted in the same application. All of the Groups involve the regulation of the vasoactive intestinal peptides. Maintaining the Examiner's restriction requirement will result in piece-meal prosecution, contrary to the policy of the MPEP and the courts. For this and the foregoing reasons, Applicants request that the restriction requirement be withdrawn.

The major reason for restriction requirements is the unduly burdensome effect in searching the art for a variety of distinct species. In this instance, although the Examiner has noted twenty-four groups, only four classes for searching have been cited by the Examiner. Searching the art would involve the body of art classified under Class 435, Subclasses 6, 7.1 and 7.2, Class 514, Subclasses 1 and 44, Class 424, Subclass 130 and Class 530, Subclass 387.1

The Claims of the instant case are directed to a method of identifying compounds and the use of these compounds. It would not have been obvious to those of ordinary skill in the art to choose the particular compounds of the present invention as a method for increasing skeletal muscle mass or function or in the treatment of skeletal muscle atrophy. According to *In re Ochiai,* 71 F.3d 1565, (Fe. Cir. 1995), "From the standpoint of patent law, a compound and all of its properties are inseparable. *Id* at 1572. "[T}he compounds and their use are but different aspects of, or ways of looking at, the same invention and consequently that invention is capable of being claimed both as new compounds or as a new method or process of bonding/priming." *Id.* at 1572. In other words, *Ochiai* holds that a compound and a method/process of using those compounds are the same invention. As such a restriction requirement separating the prosecution of compounds apart from a method of using those compounds is improper.

CONCLUSION

Attached hereto is a marked-up version of the changes made to the claims by the current amendment, wherein text which has been added is underlined and text which has been deleted is bracketed. The attached page is captioned **"Version with markings to show changes made."**

Applicants have made an election pursuant to the restriction requirements, with traverse, in accordance with the Examiner's requirement. Applicants request that the Examiner withdraw the requirements, and allow Claims 1-28.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

16. (Amended) [A] The method for increasing skeletal muscle mass or function according to Claim 27 in a subject in which such an increase is desirable, comprising:

[(a) identifying a subject in which an increase in muscle mass or function is desirable; and

[(b)] (a) administering to the subject a safe and effective amount of said compound selected from the group consisting of a VPAC receptor agonist, a compound that prolongs or augments the activation of VPAC receptors or the activation of a VPAC receptor signal transduction pathway, an expression vector encoding a functional VPAC receptor, an expression vector encoding a constitutively active VPAC receptor, a compound that increases expression of VPAC receptors, a compound that increases expression of VIP and a compound that increases expression of a VIP analog.

18. (Amended) [A] The method for treating skeletal muscle atrophy according to Claim 28 in a subject in need of such treatment, comprising:

(a) identifying a subject in need of treatment for skeletal muscle atrophy; and

(b) administering to the subject a safe and effective amount of compound selected from the group consisting of a VPAC receptor agonist, a compound that prolongs or augments the activation of VPAC receptors or the activation of a VPAC receptor signal transduction pathway, an expression vector encoding a functional VPAC receptor, an expression vector encoding a constitutively active VPAC receptor, a compound that increases expression of VPAC receptors, a compound that increases expression of VIP and a compound that increases expression of a VIP analog.